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APPLICATION NO.	FIL	ING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,801	04/04/2001		Staffan Folestad	1103326-0659	6014
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NEW YORK, NY 10036				2856	

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		As .				
	Application No.	Applicant(s)				
	09/806,801	FOLESTAD ET AL.				
Office Action Summary	Examiner	Art Unit				
	André K. Jackson	2856				
The MAILING DATE of this communi Period for Reply	cation appears on the cover sheet with	the correspondence address				
A SHORTENED STATUTORY PERIOD FO THE MAILING DATE OF THIS COMMUNION - Extensions of time may be available under the provisions of after SIX (6) MONTHS from the mailing date of this communication of the period for reply specified above is less than thirty (30) - If NO period for reply is specified above, the maximum states a Failure to reply within the set or extended period for reply any reply received by the Office later than three months af earned patent term adjustment. See 37 CFR 1.704(b).	CATION. of 37 CFR 1.136(a). In no event, however, may a repunication. l) days, a reply within the statutory minimum of thirty tutory period will apply and will expire SIX (6) MONTI will, by statute, cause the application to become ABA	oly be timely filed (30) days will be considered timely. HS from the mailing date of this communication. NDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed	d on <u>05 October 2004</u> .					
2a)⊠ This action is FINAL . 2	b)☐ This action is non-final.					
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closed in accordance with the practic	ce under Ex parte Quayle, 1935 C.D.	11, 453 O.G. 213.				
Disposition of Claims						
4) ⊠ Claim(s) <u>1-3,6-23 and 25-28</u> is/are potential (s) is/are potential (s) is/are allowed. 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) <u>1-3,6-23 and 25-28</u> is/are reference objected to. 7) □ Claim(s) is/are object to restrict or strict of the control of the con	e withdrawn from consideration.					
Application Papers						
9) The specification is objected to by the 10) The drawing(s) filed on is/are: Applicant may not request that any object Replacement drawing sheet(s) including 11) The oath or declaration is objected to	a) accepted or b) objected to be tion to the drawing(s) be held in abeyand the correction is required if the drawing(s	e. See 37 CFR 1.85(a).) is objected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119	•					
2. Certified copies of the priority of3. Copies of the certified copies of	documents have been received. documents have been received in Ap of the priority documents have been r nal Bureau (PCT Rule 17.2(a)).	plication No eceived in this National Stage				
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) 🔲 Interview Su	mmary (PTO-413)				
Notice of Draftsperson's Patent Drawing Review (P Information Disclosure Statement(s) (PTO-1449 or I Paper No(s)/Mail Date	TO-948) Paper No(s)	/Mail Date ormal Patent Application (PTO-152)				

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DETAILED ACTION

Claim Rejections - 35 USC § 103

- 1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 2. Claims 1-3,6-11,17 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. in view of Trygstad and Wong.

Regarding claim 1, Hammond et al. disclose "Spectrophotometric analysis" which has a means for feeding one sample through at least one predetermined analyzing position (Column 4, lines 1-11) and a means for temporarily fixing the sample in the analyzing position, where the fixing means comprises a first (8) and a second (12) holding part arranged at the analyzing position and where the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. Hammond et al. do not disclose where the first and second holding parts define apertures within the parts and where the first and second apertures together define an effective aperture in the closed position. However, Trygstad discloses in "Measurement of transmission spectra of pharmaceutical tablets" where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective aperture in the closed position (Figures 1 and 2; 30,36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective aperture in the closed position. By adding this feature the artisan would be able to analyze tablets of various sizes. Wong discloses in the patent entitled "A non-pressure dependency infrared absorption spectra recording, sample cell" where at the analyzing position the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed (Abstract; Columns 1 and 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where at the analyzing position the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. By adding this feature the apparatus would be able to hold the sample at one position during analyzing.

Regarding claim 2, Hammond et al. do not disclose where the first and second holding parts are located on opposite sides of the sample when in the closed position. However, Trygstad discloses where the first and second holding parts are located on opposite sides of the sample when in the closed position (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where the first and second holding parts are located on opposite sides of the

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sample when in the closed position as taught by Trygstad. By adding this arrangement the sample would remain in a stable position.

Regarding claim 3, Hammond et al. disclose where the first and second holding parts do not contact the sample in the open position (Column 12, lines 22-52).

Regarding claim 6, Hammond et al. disclose where the first and second holding parts each define a first and second compartment, which together define a predetermined volume (Figure 2).

Regarding claim 7, Hammond et al. disclose where the means for feeding samples through the analyzing position comprises one pre-alignment means for receiving and holding a sample during transport of the sample to the analyzing position (Figure 2).

Regarding claims 8 and 9, Hammond et al. do not disclose where the prealignment means comprises an elastically compressible member for flexibly engaging the sample. It is considered a design choice to have an elastically compressible member for flexibly engaging the sample to keep the sample from chipping or breaking.

Regarding claim 10, Hammond et al. disclose where the pre-alignment means comprise a spring-loaded arm for embracing the sample (Figure 2).

Regarding claim 11, Hammond et al. disclose where spring-loaded arm and a part of the feeding means are provided with an indentation for receiving the sample (Figure 1).

Regarding claim 17, Hammond et al. disclose where the sample is a solid dosage form (Figure 2).

Regarding claim 26, Hammond et al. disclose where the dosage is a tablet (Figure 2).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. in view of Trygstad and in further view of Soloman.

Regarding claim 13, neither Hammond et al. nor Trygstad disclose where the rotating feeder wheel is connected to a sample receiver, which provides the feeder with samples to be analyzed. However, Soloman discloses where the rotating feeder wheel is connected to a sample receiver, which provides the feeder with samples to be analyzed (Figures 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the rotating feeder wheel is connected to a sample receiver which provides the feeder with samples to be analyzed since it would provide an even distribution of tablets.

3. Claims 12,14-16 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. in view of Trygstad and Schilling.

Regarding claim 12, neither Hammond et al. nor Trygstad disclose where the means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample. However, Schilling discloses a means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising

at least one pre-alignment means for receiving at least one sample (Figure 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include a means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample as taught by Schilling since it would make it easier to analyze more samples in a shorter period of time.

Regarding claim 14, Hammond et al. do not disclose where the sample receiver is an on-line sample receiver and provides the pre-alignment means with samples. However, Schilling discloses where the sample receiver is an on-line sample receiver and provides the pre-alignment means with samples (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the sample receiver is an on-line sample receiver and which provides the pre-alignment means with samples as taught by Schilling since this would help to give an accurate measurement for the sample.

Regarding claim 15, Hammond et al. do not disclose where the sample receiver is an at-line sample receiver, which provides the pre-alignment means with samples. However, Schilling discloses where the sample receiver is an at-line sample receiver, which provides the pre-alignment means with samples. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the sample receiver

is an at-line sample receiver, which provides the pre-alignment means with samples as taught by Schilling since this would aid in having the measurement of the samples more accurate.

Regarding claim 16, Hammond et al. do not disclose where the at-line sample receiver comprise a conical rotating part defining the bottom of an open vessel with cylindrical geometry, where samples fall upon the conical rotating part to be sequentially aligned before entering the pre-alignment means in the feeder wheel. However, Schilling discloses where the at-line sample receiver comprise a conical rotating part defining the bottom of an open vessel with cylindrical geometry, where samples fall upon the conical rotating part to be sequentially aligned before entering the pre-alignment means in the feeder wheel (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the at-line sample receiver comprise a conical rotating part defining the bottom of an open vessel with cylindrical geometry, where samples fall upon the conical rotating part to be sequentially aligned before entering the pre-alignment means in the feeder wheel as taught by Schilling since this would make it easier to sort the tablets.

Regarding claim 25, Hammond et al. do not disclose where the sample receiver is a transport line connected on-line to an instrument which performs a tabletting process. However, Schilling discloses where the sample receiver is a transport line connected on-line to an instrument which performs a tabletting

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process (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the sample receiver is a transport line connected on-line to an instrument which performs a tabletting process as taught by Schilling since this would ease in the measuring of the sample.

Claims 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over
 Hammond et al. in view of Schilling and Trygstad.

Regarding claim 18, Hammond et al. disclose a means for temporarily fixing the sample at the analyzing position. Hammond et al. disclose that the predetermined position is the analyzing position where the sample is clamped. The claim calls for at least one predetermined analyzing position Hammond et al. disclose two analyzing positions. In the second analyzing position the sample is displaced. Hammond et al. do not disclose feeding a sample sequentially through the sample presentation apparatus. However, Schilling discloses where feeding a sample sequentially through the sample presentation apparatus (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where feeding a sample sequentially through the sample presentation apparatus as taught by Schilling since this would make it easier for the samples to be placed in the analyzing position. Hammond et al. does not disclose an open position to allow the sample to be transported to an ejection position. However, the invention of Hammond et al. has to have the holding parts open in order to eject the sample to place

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another one in place. Hammond et al. do not disclose where the first and second holding parts define apertures within the parts and where the first and second apertures together define an effective aperture in the closed position. However, Trygstad discloses where the first and second holding parts define apertures within the parts (Figures 1 and 2; 30,36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where the first and second holding parts defines apertures within the parts. By adding this feature the artisan would be able to analyze tablets of various sizes.

Regarding claim 19, Hammond et al. disclose where the measurement is performed by irradiating the sample with at least one measuring beam while the sample is temporarily fixed (Figure 2).

Regarding claim 20, Hammond et al. disclose where the measurement is an optical measurement (Abstract).

Regarding claim 21, Hammond et al. disclose where the optical measurement is carried out by means of near-infrared spectrometry (Abstract).

Regarding claim 22, Hammond et al. disclose where the optical measurement is carried out by means of near-infrared spectrometry (Abstract).

Regarding claim 23, it is considered a design choice and well within the purview of the skilled artisan to have the radiation beam a microwave beam since this would give the artisan a beam with a shorter wavelength and a more precise measurement.

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Regarding claim 27, Hammond et al. disclose a means for feeding one or more samples sequentially through at least one predetermined analyzing position, where at least one measuring radiation beam irradiates the sample when the sample is located in the analyzing position (Column 4, lines 1-11) and a means for temporarily fixing the sample in the analyzing position, where the fixing means comprises a first (8) and a second (12) holding part arranged at the analyzing position and where the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. Meanwhile, Wong discloses where at the analyzing position the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed (Abstract; Columns 1 and 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where at the analyzing position the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. By adding this feature the apparatus would be able to hold the sample at one position during analyzing.

Regarding claim 28, Hammond et al. disclose a means for feeding one or more samples sequentially through the sample presentation apparatus having at least one predetermined analyzing position, where at least one measuring radiation beam irradiates the sample when the sample is located in the analyzing

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position (Column 4, lines 1-11) and temporarily fixing the sample in the analyzing position in a closed fixed position by means of a two-piece fixing means including a first (8) and a second (12) holding part arranged at the analyzing position.

Hammond et al. do not disclose an open position to allow the sample to be transported to an ejection position. However, the invention of Hammond et al. has to have the holding parts open in order to eject the sample to place another one in place.

Response to Arguments

5. Applicant's arguments filed 10/05/04 have been fully considered but they are not persuasive.

Applicants have argued that Hammond et al. do not disclose that the first and second holding parts are configured to move between an open and closed position at the analyzing position. Hammond et al. disclose that the predetermined position is the analyzing position where the sample is clamped (Column 4, lines 1-11,23-29; Column 5 lines, 9-19,24-57). The claims call for at least one analyzing position Hammond discloses two analyzing positions. In the second analyzing position the sample is displaced. Claims 18 and 28 do not require that the holding parts be opened at the analyzing position as does claims 1 and 27. Applicants describe paragraph [0018] as not demonstrating the opened position. The Examiner agrees that the sample is clamped and then an analysis is performed on the sample by a spectrophotometer. Applicants are

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arguing that the holder is manually inserted into a "spectrometer" for analysis.

The claim is not concerned with how the sample is presented to the analysis

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

 Any inquiry concerning this communication or earlier communications from the examiner should be directed to André K. Jackson whose telephone number is (571) 272-2196. The examiner can normally be reached on Mon.-Thurs. 7AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The

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fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.J.

December 7, 2004

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